K010941

JUN 2 2 2001

EXHIBIT #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

1. **Submitter's Identification:**

Nimble Inc.
201 Millway Avenue, Unit 5
Concord, Ontario L4K 5K8
Canada

Date Summary Prepared: March, 2001

Contact Person:

Geoff Fernie, Ph.D., P. Eng., CCE
VP of Research & Development
Nimble Inc.

2. **Name of the Device:**

The Nimble Rocket Powered Wheelchair

3. **Predicate Device Information:**

Jazzy Powered Wheelchair, K#945936, Pride Health Care, Inc., Exeter, PA.

4. **Device Description:**

The Nimble Rocket Powered Wheelchair power base is a mid-wheel drive powered wheelchair. The chair has swiveling castors in front and behind the drive wheels. All four castor wheels are in contact with the ground in most circumstances. The drive wheels are mounted on a central vertically-splined shaft and are forced down on the ground by the weight of the direct-drive motors and by a compression spring. Thus, a true mid-wheeled drive function is achieved with good stability. A pressed steel unibody construction is employed with battery compartments in front and behind the drive. The chair uses a controller from Penny + Giles and steers in the usual manner by varying the speed and direction of the two driving wheels. The Rocket has an additional optional feature that allows it to be driven sideways at a low speed for precise positioning and maneuvering in confined indoor spaces.

5. **Intended Use:**

The intended use of The Nimble Rocket Powered Wheelchair is to provide mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

6. **Comparison to Predicate Devices:**

The Nimble Rocket Powered Wheelchair has similar dimensions of width and length and height. Its maximum speed is 4.25 mph which is typical, but somewhat lower than the maximum speed of other 510(k) cleared devices. Static and dynamic stability are similar, but greater than the forward stability of some approved mid-wheeled drive chairs. The Nimble Rocket Powered Wheelchair is powered by sealed lead acid batteries with a similar range to the other products. The chair rotates approximately about its true geometric centre and, therefore, has a smaller turning radius than most. The major difference is the optional capability for low speed sideways positioning maneuvers.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

a) ANSI/RESNA WC/01-1991 Wheelchair Standard, Volume I, Mechanical/Static Stability Testing

b) ANSI/RESNA WC/02-1991 Wheelchair Standard, Volume I, Mechanical/Dynamic Stability Standard

c) ANSI/RESNA WC/Volume II-1998 Wheelchair Standard for EMC Testing

d) Flame and Fire Resistance Testing (Flame Retardant Tests of the Upholstery Materials) per CAL 117 Sections A, D and E Testing

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. **Conclusions:**

The Nimble Rocket Powered Wheelchair has the same intended use and similar technological characteristics as the predicate device, the Jazzy Powered Wheelchair. Moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. The basic difference is its capability for sideways positioning maneuvers, but in all other respects, it drives like a stable mid-wheel chair using a typical controller and drive motor configuration. Thus, The Nimble Rocket Powered Wheelchair device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2001

Nimble, Inc.
Ms. Susan D. Goldstein-Falk
Official Correspondent for Nimble, Inc.
c/o MDI Consultants
55 Northern Boulevard, Suite 200
Great Neck, New York 10121

Re: K010941
Trade Name: The Nimble Rocket Powered Wheelchair
Regulation Number: 890.3860
Regulatory Class: II
Product Code: ITI
Dated: June 1, 2001
Received: June 5, 2001

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K010941

Device Name: The Nimble Rocket Powered Wheelchair

Indications For Use:

The intended use of The Nimble Rocket Powered Wheelchair is to provide mobility to persons limited to a seated position that are capable of operating a powered wheelchair.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____
(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010941